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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/252,691	02/18/1999	KEITH G WEINSTOCK	107196.135	4791

7590 12/14/2004

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/252,691	WEINSTOCK ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/17/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 29-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1-3,29-31 and 42-44* is/are allowed.

6)☐ Claim(s) *4-9,32-41 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 29-50 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

1. Claims 1-3, 29-31 and 42-44 are allowed.

Claim Objections

2. Claim 9 is objected to because of the following informalities: Claim 9 recites a "typo"; it should recite the elected invention "1394" rather than 1304. Appropriate correction is required.

Objections/Rejections Withdrawn

3. Claims objected to in paper number 33, paragraphs 11-13 are no longer objected to in light of the amendment of the claims.
4. Claims 1-4 and 29-32 rejected under 35 U.S.C. 112, first paragraph (possession and scope of enablement), as failing to comply with the written description requirement, is herein withdrawn.
5. Claims 1,3-5,7-8, 35-36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is herein withdrawn in light of the amendments of the claims and reconsideration of the issues raised.
6. Claims 3-4,7-8,31-32,34-35,40-41,44-45 and 48-49 rejected under 35 U.S.C. 102(b) as being anticipated by Rattray et al (August 1995) is herein withdrawn in light of the amendment of the claims to recite ---isolated nucleic acid---- and the traversal made of record.

Objections/ Rejections Maintained

7. Claims 4,8,32,36,41,45,49 rejected under 35 USC 101, the claimed invention lacks patentable utility, and under 35 USC 112, first paragraph, is maintained for reasons of record in paper number 33, paragraphs 9 and 10.
8. Claims 5-8,9,50,37-41 rejected under 35 U.S.C. 112, first paragraph (possession), as failing to comply with the written description requirement, is herein maintained for reasons of record in paper number 33; paragraph 15.

9. Claims 33-36,46-49 rejected under 35 U.S.C. 112, first paragraph (New Matter), as failing to comply with the written description requirement, is herein maintained for reasons of record in paper number 33, paragraph 16.

10. Claims 4-9 and 32-41, 45-50 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO 1394, a vector, and isolated host cell hat comprise SEQ ID NO 1394 or an isolated nucleic acid comprising a sequence encoding SEQ ID NO 7056 , does not reasonably provide enablement for nucleic acids that comprise at least 25 or 30 consecutive nucleic acids of SEQ ID No 1394, encode a polypeptide that shares a degree of variation relative to SEQ ID NO 7056 or SE Q ID No 1394. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, is maintained for reasons of record in paper number 33, paragraph 17.

Response to Arguments

11. The rejection of claims 4,8,32,36,41,45,49 rejected under 35 USC 101, the claimed invention lacks patentable utility, and under 35 USC 112, first paragraph, is traversed on the grounds that "the specification teaches one skilled in the art to identify the function of the polypeptides encoded by the sequences that are disclosed by consulting databases".

12. While the nucleic acid of the complete SEQ ID NO has utility as a diagnostic reagent, any amino acid sequence that does not evidence a specific, credible and substantial asserted utility or well established utility no matter what methods are taught in the instant specification to discover what biological function an amino acid sequence might have, does not define the polypeptide to be a vaccine polypeptide, a diagnostic antigen or to evidence a specific function to meet the requirement set forth under 35 USC 101. What is now claimed is a composition, and not a method of discovering the function of an encoded polypeptide. Applicant's arguments are not commensurate in scope with the instantly claimed invention. The responses made of record in paper number 33, paragraph 25 are incorporated herein by reference.

13. The rejection of claims 5-8,9,50,37-41 under 35 U.S.C. 112, first paragraph (possession), as failing to comply with the written description requirement, is traversed on the grounds that "The specification teaches that "it will be recognized by one skilled in the art that the natural translation initiation sites will correspond to ATG, GTG and TTG at page 38, lines 6-8."

14. It is the position of the examiner that while the instant specification provides general guidance for identification of a start codon, it is also an art recognized fact that polypeptides evidence internal ATG sequences, specifically internal methionines and the presence of an ATG in a sequence is not automatically an initiation sequence. Additionally, a polynucleotide sequence can be read in 6 different reading frames, specifically 3 forward and 3 backward, therefore the correct reading frame is critical to obtaining the correct polypeptide amino acid sequence. No specific subfragments of the disclosed/elected SEQ ID NO have been described, and a genus of nucleic acids that comprise at least 25 sequential bases, has not been described. The responses made of record in paper number 33, paragraph 15.are incorporated herein by reference.

15. The rejection of claims 33-36,46-49 under 35 U.S.C. 112, first paragraph (New Matter), as failing to comply with the written description requirement, is traversed on the grounds that the specification teaches "that these "ORFs may contain start codons with indicate the initiation or protein synthesis of a naturally-occurring E.cloacae polypeptide".

16. It is the position of the examiner that the specification does suggest the possibility that the disclosed ORF contain start codons, but where or which ORFs evidence an internal start codon, rather than an internal Methionine or an amino acid sequence that lacks a leader

sequence was not disclosed nor described with respect to the instantly claimed compositions of nucleic acids relative to SEQ Id NO 7056 or 1394. The responses made of record in paper number 33, paragraph 16.are incorporated herein by reference.

17. The rejection of claims 4-9 and 32-41, 45-50 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO 1394, a vector, and isolated host cell hat comprise SEQ ID NO 1394 or an isolated nucleic acid comprising a sequence encoding SEQ ID NO 7056 , does not reasonably provide enablement for nucleic acids that comprise at least 25 or 30 consecutive nucleic acids of SEQ ID No 1394, encode a polypeptide that shares a degree of variation relative to SEQ ID NO 7056 or SE Q ID No 1394. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, is traversed on the grounds that the examiner did not treat the full scope of the claim under the scope of enablement rejection.

18. It is the position of the examiner that a scope of the instantly claimed invention is enabled, while other embodiments are not enabled. Definitions provided in the instant specification were considered prior to making the scope of enablement rejection relative to the claimed nucleic acid that encodes a polypeptide. The claimed nucleic acids that comprise portions and fragments of the recited sequences that encode a polypeptide, and the asserted intended uses of the nucleic acids that encode a polypeptide with no required biological function, as now claimed have not been enabled by the instant specification. Additionally, with respect to the scope of enablement of the instant specification, the examiner has indicated allowable subject

matter within the scope of what is now claim. This allowable subject matter has been previously indicated and is also indicated herein, with respect to utilization of the recited complete SEQ ID Nos as diagnostic agents. The responses previously made of record in paper number 33, paragraph 17 are incorporated herein by reference.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
December 7, 2004

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